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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,711	12/19/2000	James W. Bacus	69570	5019

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EXAMINER

JOHNS, ANDREW W

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

09/740,711

Office Action Summary

Application No.

09/740,711

Applicant(s)

BACUS ET AL.

Examiner

Andrew W. Johns

Art Unit

2621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 6-15 is/are allowed.
- 6) ☒ Claim(s) 4, 5, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Numbering

1. The numbering of the claims fails to comply with 37 C.F.R. § 1.126, which requires that the claims be number *consecutively* beginning with the next number following the highest numbered claim previously presented. This application was filed with two different claims numbered "8," so that the claims were not properly numbered consecutively. The claims have been renumbered to comply with 37 C.F.R. § 1.126. Specifically, the second claim 8 has been renumbered as claim 9, while originally filed claims 9-16 have been renumbered 10-17. All dependencies have been similarly modified. This new numbering has been used throughout the remainder of this Action, and in order to ensure proper entry of future amendments and to avoid confusion, applicant should use this new numbering in all future correspondence.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-5 and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation, at lines 2-3 of both claim 4 and claim 5, of "the displayed image" is indefinite because the prior language of these claims and of claims 1-2 from which the both depend, fails to recite or define any displayed image or include any limitations that provide for the display of an image. Therefore, it is unclear what image is referred to and further modified

by these recitations. It is suggested that proper support for this recitation might be found in claim 3, and that amending claims 4 and 5 to be dependent from claim 3 might resolve this issue.

In addition, the recitation, at lines 10-11 of claim 16, of "...storing them with identifying them as a microarray..." is unclear and confusion. It is unclear what is stored with the images or how it identifies the images. It would appear that the claim language is incomplete, and it is suggested that amending this recitation to read "...storing them with data identifying them as a microarray..." or similar language might clarify this recitation and resolve this issue.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 17 is directed towards an apparatus for storing a microarray image that comprises a storage medium containing a plurality of digitized images and related identifying information. However, digitized images, *per se* and the related identifying information is merely descriptive material. Such images and identifying information is generally considered non-functional descriptive material, because they do not, in and of themselves, impart any functionality upon a general purpose programmable computer.

Descriptive material can only be considered statutory if it is **both** functional (i.e., it imparts specific functionality upon a computer, such as a computer program or a specific data structure arrangement) **and** it is embodied on a computer-readable medium. See the guidelines set forth in M.P.E.P. § 2106. While the storage medium set forth in claim 17 might be

considered a "computer-readable medium," this is not sufficient to render the claimed subject matter statutory. Non-functional descriptive material, such as the digitized images and identifying information defined by the claim language, is never considered to be statutory, even when embodied in a computer-readable medium.

5 Claim 17 does not include any description of any operations performed on the images or the identifying information, nor does it define any specific apparatus elements that operate thereon. Because the claim is solely directed towards the storage medium containing the non-functional data, the claimed subject matter, as a whole, is directed towards non-statutory subject matter.

10 ***Claim Rejections - 35 U.S.C. § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bacus et al. '690 (US 5,428,690 A).

20 Bacus et al. '690 teaches an apparatus for processing an image of a tissue sample including a microscope (column 5, lines 3-5; 12 in Figure 1) having a digitally controlled stage for carrying and positioning a microscope slide having a tissue sample thereon (12a in Figure 1); an imager connected to the microscope to receive at least a portion of the magnified image of the tissue sample and generating signals representative thereof (column 5, lines 8-28); a processor
25 coupled to the imager for receiving the images (column 5, lines 28-35) and storing them (156 in

Figure 9; image fields are stored) with data identifying them (Figure 17 shows the data structure stored and associated with each image, including header information that identifies an image) and identifying individual characteristics of the tissue sample (the various position records shown in Figure 17 reflect individual characteristics of the tissue samples); and a display for displaying at least a portion of one of the tissue sample images (30 in Figure 1), as stipulated by claim 16. In addition, Bacus et al. '690 further teaches an apparatus for storing such images including a storage medium (45, 46, 48 in Figure 2) containing a plurality of digitized images of identically treated tissue samples from a microscope slide (Figure 5 represents the stored image of a slide that includes two samples 88, 89 that have been identically treated), each tissue sample comprising at least one image (94 in Figure 5), each image having associated with it identifying data (Figure 17), which is also stored on the storage medium (column 6, lines 30-34; images are stored in bulk storage; as are the identifying data; column 17, lines 46-54), as stipulated by claim 17. Therefore, Bacus et al. '690 meets each of the limitations of these claims and anticipates the claimed invention.

Allowable Subject Matter

7. Claims 1-3 and 6-15 are allowed.

8. Claims 4-5 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. § 112, second paragraph, set forth in this Office action.

9. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art teaches or suggests scanning and storing a plurality of tissue samples placed in an array on a microscope slide and treated simultaneously with substantially identical treatment, as required by claim 1. Similarly, claim 10 requires selecting and displaying stored images of tissue samples placed in an array on a microscope slide and treated simultaneously

with substantially identical treatment. None of the prior art teaches or suggests these features, so that the claimed invention is allowable over the prior art.

Notice to Applicant

10. The papers filed on 22 January 2002 (with a Certificate of Mailing dated 18 December 2001) have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 C.F.R. § 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

COPY OF PAPERS
ORIGINALLY FILED

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 C.F.R. § 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 C.F.R. § 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bacus et al. '265 and Bacus et al. '930 were each cited in the specification and are

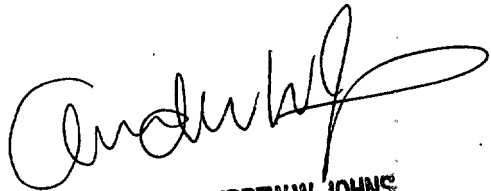
therefore made of record. Emi et al. and Kamentsky et al. each teach systems that scan and store images of tissue samples. Noblett and Stephan et al. teach the use of microarrays, but fail to suggest that the samples on these microarrays can be simultaneously treated with substantially identical treatment.

5 12. Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Andrew Johns whose telephone number is (703) 305-4788. The
examiner is normally available Monday through Friday, at least during the hours of 9:00 am to
3:00 pm Eastern Time. The examiner may also be contacted by e-mail using the address:
10 andrew.johns@uspto.gov. (Applicant is reminded of the Office policy regarding e-mail
communications. See M.P.E.P. § 502.03.)

15 If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Leo
Boudreau, can be reached on (703) 305-4706. The fax phone number this art unit is (703) 872-
9314. In order to ensure prompt delivery to the examiner, all unofficial communications should
be clearly labeled as "Draft" or "Unofficial."

20 Any inquiry of a general nature or relating to the status of this application or proceeding
should be directed to the Technology Center Customer Service Office whose telephone number
is (703) 306-0377.

25 A. Johns
2 April 2002


ANDREW W. JOHNS
PRIMARY EXAMINER